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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/715,985 | 11/18/2003 | Thomas F. Fangrow JR. | ICUMM.183A | 4879 |

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EXAMINER

GILBERT, ANDREW M

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| ART UNIT | PAPER NUMBER |
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3767

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/715,985 | Applicant(s) FANGROW, THOMAS F. | |
| | Examiner Andrew M. Gilbert | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/21/2005</u> <u>1-20-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/21/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

2. Claim 7 is objected to because of the following informalities: Claim 7 recites ":" in ln 2 instead of ".". The appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (5545143). Fischell discloses an injection assembly (200) for subcutaneous medication delivery with a base (210) having upper and lower sides (Fig 11) with the lower side of the base having an adhesive layer (230), a base cannula (221) extending downwardly from the lower side (Fig 11), a funnel shaped port (Fig 11) extending upwardly from the upper side (Fig 11) in fluid communication with the base cannula and having a septum (205) at near the upper side that seals the port from fluid flow. An introducer cap (250) having upper and lower sides (Fig 17) and a needle (251) extending downwardly from the lower side (Fig 17) can removably attach to the upper

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side of the base by at least one flat surface (252, 253) for grasping the cap and the needle can extend through the septum and through the base cannula (221) to pierce the skin while the adhesive on the base contacts the skin (col 13, lns 1-13). Furthermore, an infusion cap (240) with upper and lower sides (Fig 15) and an infusion cannula (249) extending downwardly from the lower side of the cap and an elongate flexible lumen (243) in fluid communication with the infusion cannula (249) that extends through the septum to be in fluid communication with the base cannula (221; Figs 14-16).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell. Fischell discloses the invention substantially as claimed except for the introducer cap including at least two generally flat surfaces that facilitate pinching the cap to change its shape and allow the cap to be removably engages with the base. Fischell does disclose that the infusion cap (240) has two generally flat outer surfaces (248) of the outer prongs that are squeezed together to disengage the lips (225, 247) and release the infusion cap from the base (col 12, lns 45-50) for the purpose of providing releasable attachment between the base and the infusion cap. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the introducer cap as taught by Fischell with the infusion cap as taught by Fishcell for

the purpose of providing squeezable prongs that pinch the cap and allow for releasable attachment between the base and the infusion cap.

7. Claims 6, 7, 8, 9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Douglas et al (WO 02/070037). In reference to claim 6, Fischell discloses the invention substantially as claimed except for the infusion cap having a substantially cylindrical portion. Douglas et al teaches that it is known to have an infusion cap (40) that has a substantially cylindrical portion (Figs 3-5) for the purpose of helping secure the infusion cap to the base. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the infusion cap as taught by Fischell with the infusion cap with a cylindrical portion as taught by Douglas et al for the purpose of helping to secure the infusion cap to the base.

8. In reference to claim 7, Fischell discloses the invention substantially as claimed except for the infusion cap having a substantially dome-shaped upper side. The Applicant's specification recites that the advantageous dome-shape of the infusion cap provides cover for the entire base member, thereby protecting the base member from contamination by dirt, dust, germs, or other contaminants (paragraph [0074, Ins 6-8]). Douglas et al teaches that it is known to have an infusion cap (40) that covers the entire base (14, Fig 3) for the purpose of providing rotatable housing that can turn freely while still providing continuous infusion of medication. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a infusion cap with a non-dome shape that covers the entire base member

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because the Applicant has not disclosed that a dome-shape provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the infusion cap of Douglas et al because the cap covers the entire base member and provides protection against contamination. Therefore, it would have been an obvious matter of design choice to modify the infusion cap of Fischell with the infusion cap of Douglas et al to obtain the invention as specified in claim 7.

9. In reference to claims 8, 9, and 11-13, Fischell discloses the invention substantially as claimed and additionally discloses a retaining rim, or lip (225), on the base with the introducer cap (Fig 17). However, Fischell does not expressly disclose the infusion cap having a substantially cylindrical portion, the infusion cap being a low-profile dome shape, and the introducer cap being substantially dome-shaped. Douglas et al teaches that it is known to have Douglas et al teaches that it is known to have an infusion cap (40) that has a substantially cylindrical portion (Figs 3-5) for the purpose of helping secure the infusion cap to the base (see discussion in regard to claim 6). Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the an infusion cap (40) that covers the entire base (14, Fig 3) as taught Douglas et al to be substantially dome-shaped (see discussion of claim 7).

Additionally, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the introducer cap (250, Fig 17) as taught by Fischell to be dome-shaped because the Applicant has not disclosed that the introducer cap being dome shaped provides an advantage, is used

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for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicant's invention to perform equally well with the introducer cap (250) of Fischell because the introducer cap performs the same function as the Applicant's introducer cap to pierce the skin of the patient with the introducer needle and introduce the base cannula and then be removed so that the infusion cap can be attached. Therefore, it would have been an obvious matter of design choice to modify the introducer cap as taught by Fischell to obtain the invention as specified in claim 8, 9, and 11-12.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell. Fischell discloses the invention substantially as claimed except for the introducer cap including at least two generally flat surfaces that facilitate pinching the cap to change its shape and allow the cap to be removably engages with the base. Fischell does disclose that the infusion cap (240) has two generally flat outer surfaces (248) of the outer prongs that are squeezed together to disengage the lips (225, 247) and release the infusion cap from the base (col 12, lns 45-50) for the purpose of providing releasable attachment between the base and the infusion cap. See discussion above regarding claim 3.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

KEVIN C. SIRMONS
PRIMARY EXAMINER

